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09/164,764 10/01/98 SIDRANSKY

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EXAMINER

PAWLIL, A

ART UNIT

PAPER NUMBER

1653
DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/164,764

Applicant(s)

David Sidransky

Examiner

Anna Pawul

Group Art Unit
1653



☒ Responsive to communication(s) filed on Nov 22, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 23-34 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 23-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The amendment filed on October 1, 1999 has been entered.

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 23-33 under 112 2nd paragraph has been thoroughly considered and in view of applicants arguments has been withdrawn.

Double Patenting

3. The previous rejection of claims 23-33 under 112 2nd paragraph has been thoroughly considered and in view of applicants arguments has been withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 23-26 and 28 rejected under 35 U.S.C. 102(e) as being anticipated by de la Chapelle, US Patent # 5,871,925.

De la Chapelle teaches that DNA from tumors display a change in the short repeat sequences (micro satellites) and that these differ from normal tissues (abstract and column 2, line 51-56). They also teach that the micro satellite repeats are "typically di-or tri-nucleotide repeats" (column 6, line 34-36).

In addition, de la Chapelle teaches that the DNA sample is obtained from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 27, 29-34 rejected under 35 U.S.C. 103(a) as being unpatentable over de la Chappelle et al. (US Patent 5,871,925) and further in view of Gonzalez-Zulueta et.al (Cancer

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Research, 1993), Merlo et.al (Cancer Research, 1994), and Ah-See et al..(Cancer Research, 1994).

Claim 27 is drawn to a method to detect differences in micro satellite marker length where the micro satellite marker is a tetra-nucleotide repeat.

Claims 29-33 are further limiting as they refer to a specific specimen or organ from which the DNA sample is obtained.

Claim 34 is further limiting wherein the sample is from a specimen or tumor that is external to the primary tumor or a histopathological margin sample.

The primary reference, de la Chappelle et al., discloses a method for the use of micro satellite markers to detect cancer (column 18, lines 82-96). De la Chapelle (US Patent # 5,871,925) teaches that DNA from tumors display a change in the short repeat sequences (micro satellites) and that these differ from normal tissues (abstract and column 2, line 51-56). They also teach that the micro satellite repeats are "typically di-or tri-nucleotide repeats" (column 6, line 34-36). In addition, de la Chapelle teaches that the DNA sample is obtained from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18). de la Chapelle does not teach to the use of DNA samples from primary tumors or regions near primary tumors. They also do not teach that the micro satellite markers can be tetra-nuclide repeats.

Gonzalez-Zulueta, et al address instabilities that include both tri and tetra-nucleotide repeats and both expansion and deletions of the repeat units within the micro satellite markers (

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p.5620, lines 2-8). The reference uses bladder and colorectal cancer as examples but Gonzalez-Zulueta, et al suggests that “ this kind of instability might be common to all sporadic human cancers” (Cancer Research, 53 1993 - p. 5622, column 2, line 22-29).

In Merlo et al (p. 2098 column 2, lines 11-39) micro satellite sequences are examined in both tumors and normal tissues of the lung. Differences in the micro satellite markers are examined by amplification via PCR. The tumors that are examined are primary tumors.

Ah-See et.al teaches using micro satellite markers to analyze cancers of the head and neck (p.1617, column 1, lines 3-7).

The examiner takes note that the preceding references do not use a fluid specimen that has come from the organ in question. de la Chapelle teaches that the DNA sample is obtained from blood or any other body tissue from which DNA can be obtained (column 3, line 57 and column 5, line 17-18. Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of de la Chapelle pertaining to changes in micro satellite markers to detect cancer, with tetranucleotide changes in micro satellite sequences taught by Gonzalez and its application in primary tumors and organ specific tumors taught by Merlo and Ah-See to achieve the claimed inventor as a whole. One of ordinary skill in the art would have been motivated to achieve detection of tumors in sample for diagnostic and prognostic purpose as taught by de la Chapelle (see abstract).

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Response to Amendment

Claim Rejections - 35 USC § 102

8. Applicant's argument has been thoroughly considered and found to be unconvincing. Examiner agrees that looking at a mutation in the hMSH2 gene locus and looking at a phenomenon are different. However, Applicant's argument is not convincing because de la Chappelle et al. (US 5,871,925) teach that one can look at a body fluid to pick up these mutations (col.5, lines 16-29, 47-52). De la Chapelle et al. teach the use of blood, amniocytes or other body tissue or sample containing DNA (col.5, lines 16-29, 47-52). This encompasses a body fluid which drains an organ. De la Chapelle also teach that the method disclosed here is useful for detecting a predisposition for cancer by examining the microsatellite marker length. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

9. Applicant's argument has been thoroughly considered and found to be unconvincing. de la Chappelle (US 5,871,925) teaches the use of a body fluid to analyze mutations (col.5, lines 16-29, 47-52). Applicant's argument is not convincing because de la Chappelle et al. (US 5,871,925) teach that one can look at a body fluid to pick up these mutations (col.5, lines 16-29, 47-52). De la Chapelle et al. teach the use of blood, amniocytes or other body tissue or sample

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containing DNA (col.5, lines 16-29, 47-52). This encompasses a body fluid which drains an organ. The fact that the secondary references do not teach the use of a body fluid does not render this nonobvious because of the teaching of de la Chappelle. Therefore the rejection is maintained.

10. This action is made FINAL.

11. 1.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pawul whose telephone number is (703) 305-0806. The examiner can normally be reached Monday-Friday 7:30 AM to 4:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be normally reached on Monday-Thursday from 8:00 AM to 5:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to group 180 via the PTO Fax Center located in Crystal Mall 1. Papers may be submitted Monday-Friday between 8:00 AM and 4:00 PM (EST). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (703) 305-3014 or (703) 308-4242.


EGGERTON A. CAMPBELL
PRIMARY EXAMINER

AP
1-18-2000